Executive Summary Report on the USPTO Biotechnology/Chemical/Pharmaceutical (BioChemPharma) Customer Partnership Meeting on March 3, 2009

The first 2009 BioChemPharma Customer Partnership quarterly meeting was held at the U.S. Patent & Trademark Office (USPTO) on March 3, 2009, in Alexandria, VA. This Report is a short synopsis of the meeting, along with additional notices. If you wish to have a bound copy, as well as the attachments, please contact Raymond Van Dyke. Electronic copies are also available.

The session topics discussed at the meeting included the following: (1) patent term extension; (2) chemical unity of invention practice; (3) 35 U.S.C. §112, 6th paragraph training; (4) topics in viral immunology; and (5) update on gene therapy and transgenics.

Below are brief summaries of the session topics that were covered at the meeting:

1. Patent Term Extension (PTE) Under 35 U.S.C. §156. In the first morning session, Mary Till, Esq., Legal Advisor of the Office Patent Legal Administration, discussed patent term extension under 35 U.S.C. §156, its statutory requirements, scope, limitations, requirements by the applicant, duties of the Director, term limitations, extension of terms, interim extensions and USPTO processing of PTE applications.

For combination products, if any one active ingredient of such products has not been previously approved, it can form the basis of a PTE, provided the patent claims that ingredient.

If a patent will expire prior to product approval, it is possible to file an interim extension for the patent, provided that the product must be in the approval phase. There are two types of interim extensions available, both of which are in accordance with 35 U.S.C. §156(d)(5) and §156 (e)(2). However, failures in compliance with any of the statutory requirements under 35 U.S.C. §156 would likewise result to the USPTO's inability to grant an interim extension pursuant to 35 U.S.C. §156(e)(2). See, e.g., *Somerset v. Dudas*, (Fed. Cir. 2007).

Ms. Till also touched on two hotly-contested statutory criteria, which include: (1) definition of a "product" (as set forth in 35 U.S.C. §156(a)(5)(A), §156(f)(1) and §156(f)(2)); and (2) a 60-day application filing period (as set forth in 35 U.S.C. §156(d)(1)).

For example, under the first criteria, a drug product is defined as "an active ingredient of a new drug…including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient" (35 U.S.C. §156 (f)(2)). However in *Photocure v. Dudas* (E.D. Va), the USPTO denied Photocure's PTE application for METVIXIA® (methyl aminolevulate hydrochloride), on the ground that another drug, LEVULAN® (aminolevulinic acid hydrochloride), contained the same active ingredient, ALA, as in METVIXIA® and was approved earlier for commercial marketing. Thus, METVIXIA® cannot be the first commercial marketed drug containing ALA as an active ingredient. This case is still pending and is awaiting a decision based on a December 2008 summary judgment motion.

The second criteria relates to a 60-day application filing window where it requires the owner of the patent to file an application within the 60-day period beginning on the date the product received permission.

Ms. Till also provided numerous useful information and on-line resources, all of which are included at the end of her outline.

2**. PCT Unity of Invention with Pharmaceutical and Chemical Examples.** In the next presentation, TC1600 Quality Assurance Specialist (tQAS) Julie Burke continued her series of talks on restriction practice focusing this time on the PCT unity of invention requirement, with pharmaceutical and chemical examples taken from the PCT International Search and Preliminary Examination (ISPE) Guidelines. Ms. Burke discussed how PCT unity of invention applies in different stages of PCT filings and in terms of "*a priori*" and "*a posteriori*," various categories of invention, Markush practice, intermediate and final products, combination/subcombination and rejoinder practice.

PCT Rules 13.1 and 13.2 set forth the requirements for unity of invention and the circumstances in which the requirement is considered to be fulfilled. For an international application claiming a group of inventions, unity of invention exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. The special technical features refer to those technical features that define a contribution, which each of the claimed inventions considered as a whole, makes over the prior art, with respect to novelty and inventive step.

Examples where there is unity or lack of unity of invention either "*a priori*" or "*a posteriori*" are provided in Examples A-D of her talk. Particular additional situations where the method for determining unity of invention contained in PCT Rule 13.2 is explained in greater extent are (1) combinations of different categories of claims (see Example E); Markush practice (Examples F-I); and intermediate and final products (Example J). Examples of how unity of invention applies in combination and subcombination situations are provided in Examples K and L.

The last portion of Ms. Burke's talk focused on the requirements for election during original presentation of an international patent application filed under 35 U.S.C. §371, means of traversing the election requirement to preserve the right to petition under 37 C.F.R. §1.1144 and rejoinder.

When issuing a requirement for election during original presentation, an Examiner should apply Form Paragraphs 18.21 and 18.22. In traversing a unity of invention requirement, an applicant should not only elect an invention and timely traverse the requirement, but should also provide reasons supporting the traversal.

As set forth in MPEP 821.04 *et seq*., a rejoinder is considered for non-elected invention when all the claims drawn to the elected invention are allowable. In the case of rejoining a non-elected product or process claims, all the limitations of the allowable product or process claim are required in the non-elected claims. The same practice applies to any non-elected processes of making and/or using an allowable product. In the allowance of a generic claim, applicant will be entitled to consideration of claims drawn to additional species so long they are written in dependent form or they should recite all the limitations of the allowable generic claim.

In addition to her outline, Ms. Burke also provided a table that compares U.S. restriction practice from the PCT unity of invention practice and a word document that contains form paragraphs to guide the examiners in the issuance of PCT unity of invention requirement.

3. **35 U.S.C. §112, Sixth Paragraph, MPEP 2181-2186**. In the last morning session, Quality Assurance Specialist Jean Witz of TC1600 went over the meaning of means-plus (or step-plus)-function language, requirements of §112, Sixth Paragraph, necessary steps taken by the Examiner if claim language does or does not fall under §112 Six Paragraph, and Applicant's response to Examiner's presumption that a claim limitation does or does not invoke §112 Six Paragraph.

A means-plus (or step-plus)-function limitation must recite a function to be performed rather than a definite structure or materials for performing that function. In *Phillips v. AWH Corp*., 75 USPQ2d 1321 (Fed. Cir. 2005), the Federal Circuit in an *en banc* decision expressly recognized that the USPTO employs the "broadest reasonable interpretation" when examining pending claims in a patent application. However, based on the Federal Circuit's *en banc* decision *In re Donaldson*, 29 USPQ2d 1845 (Fed. Cir. 1994), an examiner shall interpret a §112 Six Paragraph "means or step plus function" limitation in a claim as limited to the corresponding structure, materials or acts described in the specification and equivalents thereof.

To confirm whether a claim limitation invokes §112 Six Paragraph, an examiner has to apply a three-prong test. To pass this test, the three requirements to be met include (1) claim limitations must use the phrase "means for" or "step for;" (2) the "means for" or "step for" must be modified by functional language; and (3) the "means for" or "step for" must not be modified by sufficient structure, material, or acts for achieving the specified function.

To rebut the presumption that the claim limitation was not intended to be treated as means-plus-function, an applicant must either amend the claims to include any of these two phrases in accordance with the patent guidelines; and show that that even in the absence of such phrase usage, the claim limitation is written as a function to be performed and does not recite sufficient structure, material or acts which would preclude the application of §112 Six Paragraph. Ms. Witz also provided an example of how the three-prong test can be applied.

Ms. Witz also discussed the examining practice and procedure (with respect to lack of novelty (§102), obviousness (§103), inadequate written description (§112, ¶1) and lack of or insufficiency of disclosure (§112, ¶2) of the structure, material or acts for performing the claimed function) and conditions, where a prior art element is an equivalent structure of the corresponding element disclosed in the specification.

The examination guidelines for claims reciting a "means or step plus function" limitation in accordance with 35 U.S.C. §112 Six Paragraph is available at www.uspto.gov/web/offices/pac/dapp/pdf/exmgu.pdf.

4. **Topics in Viral Immunology**. In the afternoon, SPE Bruce Campbell spoke on the classification of the viruses and their implications for patentability with respect to obviousness, enablement and written description. He cited two examples of viruses belonging to the family of Potyviridae (potyvirus) and Herpesviridae (herpesvirus). Viruses can be further classified in terms of their traditional and molecular taxonomy, subfamily, genera, species, coat protein sequence, nature of genome, genome size, genome organization, presence of envelope, morphology, host range, shape, and types of diseases that they produce. Yet there are also unassigned viruses, e.g., unassigned genus of ictalurid herpes-like viruses (1 species, channel catfish virus) and 47 unassigned species capable of infecting mammals, fish, birds, reptiles and mollusks.

For example, in comparing a claim that is directed to a method of vaccinating CPV-1…with a prior method of vaccinating a CPV-2 by [the same method as claimed], can one consider the claimed method as being obvious over the prior art? The answer depends on the type of virus being claimed and other factors, as mentioned above.

With respect to enablement and obviousness, the Examiner has to consider the Wands analysis and Graham Factors when examining the claimed invention. Is predictability of the art present when comparing the claimed invention with the prior art? Because of the above-mentioned complexities among viruses, the Examiner has to conduct a background search on the virus(es) in question.

Is genomic sequence information necessary or sufficient to meet the written description requirement of the claims? For example, written description requirement has been met where an issued claim contains no sequence data (see slide 27) but sufficient information was provided and adequately supported in the specification. In another example, as shown in slide 28, a broad antibody claim contains genomic sequence information of the virus, but there is no proper description and identity of the virus, type of mammal that the virus would infect, nor antigen to which the antibody would react. Under the second example, the Examiner would be unable to allow this claim even if the genome sequence has been provided.

To overcome indefiniteness in a claim reciting an HIV NEF protein, wherein such protein is well known in the art, one approach is to include a sequence identification (SEQ ID) number that has the same amino acid residue located at the same position of the claimed HIV NRF protein. Another approach is to bring in sequence data by incorporation by reference.

According to SPE Campbell, every case presents a unique fact situation. Moreover, there are no *per se* rules since all viruses vary greatly from one another.

5. **Intellectual Property Protection for Plants in the United States**. SPE Anne Marie Grünberg of Art Units 1661 and 1638 spoke on patent protection for plants in the United States, its legal history, and patentability issues when examining plant utility patent claims. Three available types of plant protection include Plant Patent Act (PPA), Plant Variety Protection Act (PVPA) and Utility Patent to a Plant (UPP), and each of them were individually discussed. Plant patent representative claims filed under each type of plant protection are provided. Also covered in the talk are (1) examination procedures; (2) patentability requirements; (3) patentability issues, e.g., novelty, non-obviousness, restriction practice (for plant utility patents); utility and statutory invention; written description, enablement, and definiteness for each type of plant patent representative claims.

Answers as to which type of plant protection is the best depend on the business model, type of plant, how much protection is needed and how much money one has. In view of these factors, SPE Gruenberg provided a table that compares plant protection under PPA, OVPA and UPP. She also discussed the differences between utility patent versus plant patent protection. Also covered in her talk include agronomic objectives of plant utility patents, overview of commercial agricultural products, and the growth of genetically modified plants around the world.

SPE Gruenberg also provided a brief background on Art Units 1161 and 1638, rights to priority based upon application for Plant Breeder's Rights (MPEP 1613).

5. Animals and Transgenesis. Peter Paras, SPE of TC1632 gave a talk on transgenic animals and how claims directed to transgenic animals are examined and considered. The first part of SPE Paras' talk focused on (1) definitions of terms such as transgenes, transgenic animals and phenotypes; and (2) types of transgenic animals and how transgenes are introduced into the transgenic animals.

Examples of transgenic animals include over-expressers, knockouts/knockins, and nuclear transfer animals. For each of these examples, SPE Paras discussed the method of introduction of the transgene into the animal, its limitations, and unpredictability of phenotypes.

The second part of SPE Paras' talk relates to common examination issues in animal patents. These examination issues include 35 U.S.C. §101 (utility and statutory invention); 35 U.S.C. §112, first paragraph (enablement and written description), 35 U.S.C. §103 (obviousness) and novelty (35 U.S.C. §102).

A disclosed utility in animal patents must be based upon specific (particular) combination of elements (transgene + animal + phenotype). Various sample claims for animal patents and their considerations in view of each of the specific examination issues are also covered in the second part of SPE Paras' talk.

7. Other PTO-Related News. In addition to providing an executive summary of the quarterly partnership meeting, we include herein additional news that relate to the patent field.

Deferred examination of patent applications is adopted in many intellectual property (IP) offices around the world. This is not the case in the U.S., wherein mere filing and payment of the applicable fees is effectively a request for substantive examination of the application. The Patent Office conducted a roundtable on February 12, 2009 to determine whether the support for some type of deferral examination is isolated or general within the patent community and/or the public sector. See *Request for Comments and Notice of Roundtable of Deferred Examination of Patent Applications*, 74 FR 4946 (Jan 28, 2009), 1339 *Off. Gaz. Pat. Office* 153 (Feb. 21, 2009) (notice). Written comments by the public on issues raised at the roundtable or on any issue pertaining to deferred examination were welcomed by the Patent Office and will be available at the Office of the Commissioner of Patents and the USPTO Internet Web site. The roundtable web cast and its video recording are both available on the USPTO Internet Web site**.** To allow more time for the public to view the roundtable web cast, the Patent Office has extended the deadline for the receipt of written comments to May 29, 2009.

The Patent Office has issued a March 16th notification reminding Applicants that certain International Search Authorities (ISA) have limited competency for searching certain subject matter of the claimed invention. By doing so, a significant delay in the issuance of the International Search Report and Written Opinion of the ISA will happen, which, in turn, would prompt the United States Receiving Office to notify the Applicant and invite the Applicant to select a competent ISA. To read more about the notice, please go to www.uspto.gov/web/offices/pac/dapp/opla/preognotice/20090313_epo-ipau.pdf.

Patent Office Rules and Procedures. On March 20, 2009, the Federal Circuit issued its decision which addresses whether the "Claims and Continuation Final Rules (Final Rules)" falls within the scope of the USPTO's rulemaking authority (procedural or substantive in nature) and whether the Final Rules are consistent with 35 U.S.C. §120 of the Patent Act. This decision originates from Patent Office's appeal of the April 1st 2008 decision made by the U.S. District Court for the Eastern District of Virginia to permanently enjoin the Patent Office from implementing the Final Rules. The Patent Office promulgated the Final Rules on August 21, 2007, in an attempt to limit both the number of continuation applications that may be filed and

the number of claims that maybe included within each application, among other things. The intended effective date of the Final Rule was November 1, 2007. However, these rules were preliminary enjoined by the Eastern District Court of Virginia on October 31, 2007. The consolidated suits against the Patent Office were brought by plaintiffs, Smith Kline Beecham Corporation (GlaxoSmithKline) and Triantafyllos Tafas (captioned as *Tafas v. Dudas* and now *Tafas v. Doll*).

On appeal, the Federal Circuit has concluded that Final Rules 75 (the number of claims that can be filed per patent application as a matter of right before the requirement of an Examination Support Document (ESD)), 78 (limitation of the number of continuation patent applications that an applicant can file), 114 (the number of requests for continued examination) and 265 (requirement for an ESD) are procedural rules. While the Federal Circuit considered Rules 75. 114, and 265 as being consistent with the Patent Act, Rule 78, however, does conflict with 35 U.S.C. §120, and hence, is invalid. Thus, the Federal Circuit has affirmed-in-part, vacated-in-part the District Court's ruling. The *Tafas v. Doll* case has been remanded to the lower court for further proceedings consistent with the Federal Court opinion.

The issues that were not decided by the Federal Court include whether any of the Rules are (1) arbitrary or capricious; (2) conflict with the Patent Acts in ways not addressed by the Federal Circuit; (3) all Office rulemaking is subject to the notice and comment rulemaking; (4) permissibly vague; and (5) impermissibly retroactive. While waiting for the outcome of the District Court's decision, the Final Rules are still enjoined.

8. Conclusion. The tentative date for the 2009 Second Quarterly BioChemPharma Customer Partnership Meeting is June 10, 2009.

Hopefully, this Report is helpful and instructive. Dr. Cecilia A. Lopez-Chua assisted greatly in the preparation of this Report. Should you have any questions or observations, please let me know. Should you wish a copy of the attachments, please feel free to contact me.

We shall follow up with additional reports in the near future, e.g., the ongoing efforts in patent reform, which at this moment is likely to stall out again this year in view of the Supreme Court nominee confirmations. Please note for your records my new address and contact information, which as you can see is adjacent the U.S. Patent & Trademark Office.

Raymond Van Dyke
Merchant & Gould
225 Reinekers Lane, Suite 560
Alexandria, VA 22314
Office: 202.326.0311
Fax: 202.326.0355
vandyke@merchantgould.com
vandyke@acm.org